(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 July 2005 (14.07.2005)

PCT

(10) International Publication Number
WO 2005/063126 A2

(51) International Patent Classification[7]: A61B 10/00

(21) International Application Number:
PCT/US2004/043021

(22) International Filing Date:
20 December 2004 (20.12.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/532,277	23 December 2003 (23.12.2003)	US
11/014,413	16 December 2004 (16.12.2004)	US

(71) Applicant *(for all designated States except US)*: **SENORX, INC.** [US/US]; 11 Columbia, Suite A, Aliso Viejo, CA 92656 (US).

(72) Inventors: **SHABAZ, Martin, V.**; 25421 Old Trabuco, Lake Forest, CA 92630 (US). **QUICK, Richard, L.**; 22970 Bouquet Canyon, Mission Viejo, CA 92692 (US). **LOUW, Frank, R.**; 6188 Paseo Tienda, Carlsbad, CA 92009 (US). **LUBOCK, Paul**; 30 Bethany, Laguna Niguel, CA 92677 (US). **SAFABASH, Jason, H.**; 30 Torres Pointe, Aliso Viejo, CA 92656 (US).

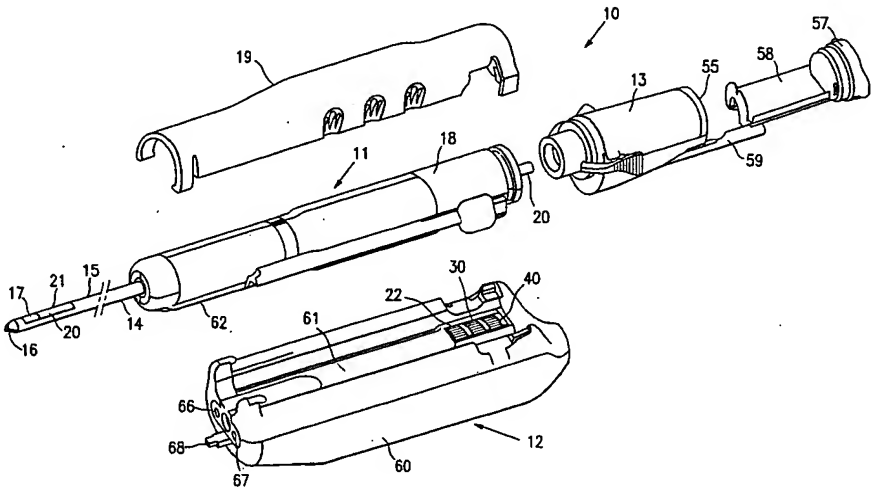
(74) Agent: **LYNCH, Edward, J.**; Duane Morris LLP, One Market, Spear Tower, Suite 2000, San Francisco, CA 94105 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: BIOPSY DEVICE WITH APERTURE ORIENTATION AND IMPROVED TIP FIELD OF THE INVENTION



(57) Abstract: The invention is directed to a system and device for separating and collecting a tissue specimen from a target site within a patient. The device includes a probe component which is releasably secured to the driver component. The probe component has an elongated tubular section, a penetrating distal tip and a tissue receiving aperture in the distal end of the tubular section proximal to the distal tip, and a tissue cutting member which is slidably disposed within the probe member to cut a tissue specimen drawn into the interior of the device through the aperture by applying a vacuum to the inner lumen of the tissue cutting member. The driver has drive members for operating the elements of the probe component. The tissue penetrating distal tip preferably has a triple concave curvature shape with three curved cutting edges leading to a sharp distal point.

WO 2005/063126 A2

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

BIOPSY DEVICE WITH APERTURE ORIENTATION AND IMPROVED TIP

FIELD OF THE INVENTION

[0001] The present invention relates generally to tissue removing devices such as biopsy devices and the methods of using such devices. More specifically, it is directed to an improved device and method for accessing and removing pathologically suspect tissue from within a patient's body.

BACKGROUND OF THE INVENTION

[0002] In diagnosing and treating certain medical conditions, such as potentially cancerous tumors, it is usually desirable to perform a biopsy, in which a specimen of the suspicious tissue is removed for pathological examination and analysis. In many instances, the suspicious tissue is located in a subcutaneous site, such as inside a human breast. To minimize surgical intrusion into the patient's body, it is desirable to be able to insert a small instrument into the patient's body to access the targeted site and to extract the biopsy specimen therefrom.

[0003] Electrosurgical techniques have been used in a variety of biopsy procedures. In electrosurgery, high frequency electrical energy is typically applied to patient tissue through an active electrode, the electrical circuit being completed by a return electrode in contact with the patent's tissue. Electrical energy flowing through the tissue from the active electrode is effective to ablate tissue near the active electrode, forming an opening in the tissue and so allowing insertion of the instrument into a patient's body. A return electrode may be placed on the exterior of the patient's body or may be incorporated into the device itself. The return electrode is typically attached to the patient at a point remote from where the primary or active electrode contacts the tissue. However, in the case of a bipolar electrode for

example, the return electrode may be disposed near to the active electrode. An electrosurgical biopsy instrument is disclosed and claimed in United States Patent Application Serial No. 09/159,467 for "Electrosurgical Biopsy Device and Method," now U.S. Patent No. 6,261,241, assigned to the assignee of the present application, and which is hereby incorporated by reference in its entirety. A variety of needle like tip designs have been developed to aid in the accessing of intracorporeal sites for biopsy and other procedures. Electrosurgical techniques have also been used in a variety of biopsy procedures to gain access to an intracorporeal site. See for example U.S. Patent No. 6,261,241, assigned to the assignee of the present application, and which is hereby incorporated by reference in its entirety.

[0004] The prior needle like tips do not always allow proper placement of the biopsy or other surgical device. Moreover, while the electrosurgical biopsy devices have been found to be effective in many instances, they are not suitable for use in conjunction with magnetic resonance imaging.

[0005] While these electrosurgical biopsy devices have been found to be effective in many instances, they may not always be suitable for use in conjunction with magnetic resonance imaging.

SUMMARY OF THE INVENTION

[0006] This invention is directed to devices for accessing and severing tissue from a target site within a patient and methods for utilizing such devices. The devices embodying features of the invention provide access to a targeted tissue site within a patient and provide for the selection, separation and capture of a tissue specimen from supporting tissue at the targeted site.

[0007] A tissue accessing and severing device and system having features of the invention generally include an elongated, preferably disposable probe component

having a plurality of operative elements and a driver component configured to receive the elongated probe component and drive the various operative elements of the probe component.

[0008] The elongated probe component has a distal shaft portion with a tissue penetrating distal tip, a tubular section proximal to the distal tip, an inner lumen extending within the tubular section and an open, tissue receiving aperture in the tubular section which provides access to tissue at the targeted site. The probe component includes an elongated tissue-cutting member, which is preferably at least in part cylindrically shaped. The tissue cutting member is provided with at least one tissue cutting edge which is configured to sever tissue extending into the interior of the tubular section through the aperture thereof. The cutting edge on the tissue cutting member may be configured for longitudinal cutting movement and may include oscillating rotational motion and/or reciprocating longitudinal motion to sever specimen tissue extending through the aperture from supporting tissue at the targeted site. The cutting surfaces or edges are radially spaced from a longitudinal axis of the probe component and are generally transversely oriented with respect to the longitudinal axis. The tissue cutter is preferably slidably disposed within the inner lumen of the tubular section, although it may be disposed about the tubular section. The probe component may also have a handle which releasably engages the driver component.

[0009] In one embodiment of the invention, the cutting member has an inner lumen preferably extending to the proximal end thereof for tissue specimen removal. While mechanical withdrawal of the tissue specimen may be employed, it is preferred to provide a vacuum within the cutting member from the proximal end of the cutting member. The proximal end of the cutting member may be configured to

be in fluid communication with a vacuum source to aspirate the severed tissue specimen through the inner lumen of the cutting member to a tissue collection station. A higher fluid pressure may be maintained in the inner lumen of the cutting member distal to the tissue specimen to aid in transporting the specimen proximally through the inner lumen. In this manner, the mechanical withdrawal and/or the vacuum on the proximal end of the specimen and a higher pressure on the distal end of the specimen can move the specimen through the inner lumen of the cutting member to a tissue collection station.

[0010] In at least one embodiment, the handle of the probe component is secured, preferably releasably secured, to the driver housing provided to operably connect the various operative elements of the probe with operative elements of the driver component. The tissue cutting member is operatively connected to at least one driver to provide the desired cutting motion. The proximal end of the tubular section is rotatably secured within the handle housing so that the orientation thereof with respect to the longitudinal axis and therefore the orientation of the tissue receiving aperture within the tubular section, can be selected. The orientation of the aperture may be selected manually such as described in copending application Serial Number 10/642,406, filed February August 15, 2003 or it may be preset or selected electronically by a control module which also controls the operation of the cutting member and electrical power. The aperture orientation setting may be selected before or after the distal portion of the probe component is inserted into the patient.

[0011] The tissue penetrating distal tip embodying features of the invention has a proximal base secured to the distal end of the probe shaft of the biopsy device, and a sharp distal point distal to the proximal base. The tissue penetrating distal tip has a first concave surface extending from the base to the sharp distal point. The distal

tip also has a second concave surface, which intersects the first concave surface forming therewith a first curved cutting edge that leads to the sharp distal point. The distal tip also has a third concave surface which intersects the first concave surface forming therewith a second curved cutting edge leading to the sharp distal point and also intersects the second concave surface forming therewith a third curved cutting edge that leads to the sharp distal point. The concave surfaces preferably have center lines which extend from the proximal base of the distal tip to the sharp distal point. In a presently preferred embodiment the concave surfaces are of the same area. However, they may have different areas.

[0012] The driver component has at least two and preferably three driver units for operating the probe component secured to the driver component. Specifically, the driver component has a first driver unit for rotating the tubular section of the probe component, a second driver unit for moving the cutting member along a longitudinal axis of the cutting member and optionally a third driving unit for rotating or oscillating the cutting member about the longitudinal axis. The first driver unit rotates the tubular section of the probe component, preferably in discrete steps, so that the location of the tissue receiving aperture in the distal extremity of the tubular section can be selected prior to or during the procedure. The discrete rotational steps of the tubular section are preferably in 30° or multiples thereof so that the rotational movement will follow 12 hour clock markings. Preferably, the second and third driver units are operable together so that the cutting member may rotate or oscillate about a longitudinal axis as the cutter member is moved longitudinally. This allows a rotation or an oscillation of the cutter during the cutting process which can aid in cutting tissue.

[0013] The driver component may have one or more light sources in a distal portion thereof to illuminate the accessing site during the procedure.

[0014] A method of cutting and collecting a tissue specimen with a tissue collection device embodying features of the invention includes advancing such a device at least partially into tissue at a desired site within the patient's body with the tissue penetrating distal tip of the outer cannula disposed distal to the tissue specimen to be separated from the target site. A vacuum is established within the inner lumen of the tubular section to draw tissue through the aperture therein into the inner lumen of the tubular section. The cutting member, which is slidable disposed within the inner lumen of the tubular section, may then be moved longitudinally to cut a tissue specimen from supporting tissue at the target site by the longitudinal motion, which preferably includes oscillating rotational movement and/or reciprocating longitudinal movement. The vacuum established within the inner lumen of the tubular section may be applied through the inner lumen of the tissue cutting member when the tissue cutting member is disposed within the tubular section. The applied vacuum within the inner lumen of the tissue cutting member, may also be utilized to pull or aspirate the separated tissue sample proximally. In addition, or alternatively, a higher fluid pressure may be maintained in a distal part of the inner lumen of the tubular section, distal to the specimen, to push the tissue specimen proximally, Alternatively, the tissue specimen may be mechanically withdrawn. Fluid pressure may include pressure from a liquid delivered into the interior of the device, such as a physiological saline solution, and may include a gas, such as pressurized carbon dioxide, nitrogen or air, delivered into the interior of the device. Access to ambient air can also maintain a sufficiently high pressure differential to move the specimen through the inner lumen of the cutting member. Anesthetic may be injected to the

target site through the outer cannula or the inner lumen of the cutting member. Upon removal from the patient, the tissue specimen may then be subjected to pathological examination. After acquisition of a tissue specimen or specimens, the tissue separation system may be repositioned for further tissue separation and collection or it may be withdrawn from the patient.

[0015] The tubular section of the probe provides the support for the probe to enable precise location of the accessing port to the desired location at the target site with its radial orientations being preset before the device is introduced into the patient or selected after the tubular section is disposed within the patient. The cutting member quickly and cleanly severs the tissue specimen drawn into the interior of the tubular section though the aperture by the action of the vacuum or otherwise. Upon removal of the tissue specimen, the tissue receiving aperture may be radially repositioned about the longitudinal axis of the tubular section of the probe component so that a plurality of specimens may be taken from the target site. The orientation of the tissue receiving aperture during the procedure may follow a preselected pattern or may be selected by the physician for other selected tissue specimens.

[0016] A tissue acquisition system assembly embodying features of the invention may include a device for delivery of one or more marker bodies through a tubular member of a biopsy device such as the tubular cutting member. Such a marker delivery device includes an elongated shaft having an inner lumen and a discharge opening in a distal portion of the elongated shaft, at least one marker body which is disposed within the inner lumen of the elongated shaft, a pusher element which is slidably disposed within the delivery device and which is configured to urge at least one marker body out the discharge opening in the distal portion of the elongated

shaft. The marker delivery device has a distally flared guide member which is slidably disposed on the elongated shaft to guide the distal portion of the elongated shaft into a proximal end of the tubular member of a biopsy device. This invention is directed to a tissue penetrating probe tip, particularly for biopsy devices. These devices provide access to a targeted tissue site and provide for the separation and capture of a tissue specimen from supporting tissue at the targeted site.

[0017] These and other advantages of the invention will become more apparent from the following detailed description of the invention and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] Figure 1 is an exploded view of the elongated tissue biopsy system embodying features of the invention.

[0019] Figure 2 is a perspective view of the embodiment shown in Figure 1 in an assembled condition without a housing cover for the probe component.

[0020] Figure 3 is a side elevational view of the tissue biopsy device shown in the Figure 2.

[0021] Figure 4A is a longitudinal cross-section of the probe shown in Fig. 3 taken along the lines 4-4 with the tissue cutting element in a withdrawn position.

[0022] Figure 4B is a longitudinal cross-section of the probe shown in Fig. 3 taken along the lines 4-4 with the tissue cutting element in a forward or closed position.

[0023] Figure 5 is a transverse cross-sectional view of the probe shown in Figure 4B taken along the lines 5-5.

[0024] Figure 6 is a perspective view of the underside of the probe shown in Figure 1.

[0025] Figure 7 is an enlarged perspective view of the distal end of the driver unit shown in Figure 1.

[0026] Figure 8 is an enlarged perspective view of the distal end of the probe housing illustrating a marker element which depicts the orientation of the aperture in the tubular section of the biopsy device.

[0027] Figure 9 is a perspective view of the underside of the driver shown in Figure 1.

[0028] Figure 10 is an elevational view of a tissue penetrating tip embodying features of the invention.

[0029] Figure 11 is a perspective view of the underside of the tip shown in Figure 10.

[0030] Figure 12 is a longitudinal, center line cross-sectional view of the penetrating tip shown in Fig. 10.

[0031] Figure 13 is a longitudinal cross-sectional view of the penetrating tip shown in Figure 12 taken along the lines 13-13.

[0032] Figure 14 is a longitudinal cross-sectional view of the penetrating tip shown in Figure 12 taken along the lines 14-14.

[0033] Figure 15 is a longitudinal cross-sectional view of the penetrating tip shown in Figure 3 taken along the lines 15-15.

[0034] Figure 16 is a bottom view of the penetrating tip shown in Figure 10.

[0035] Figure 17 is a transverse cross-sectional view of the penetrating tip shown in Figure 16 taken along the lines 17-17.

[0036] Figure 18 is a transverse cross-sectional view of the penetrating tip shown in Figure 16 taken along the lines 18-18.

[0037] Figure 19 is a transverse cross-sectional view of the penetrating tip shown in Figure 16 taken along the lines 19-19.

[0038] Figure 20 is a transverse cross-sectional view of the penetrating tip shown in Figure 16 taken along the lines 20-20.

[0039] Figure 21 is a perspective view of the tissue biopsy system shown in Figure 1 assembled and mounted on a stereotactic frame.

[0040] Figure 22 is an elevational view of a marker delivery device with a flared guide on the distal end of the shaft which facilitates guiding the distal tip of a marker delivery device into the interior of the proximal end of the tissue cutter.

[0041] Figure 23 is a longitudinal cross-sectional view of the distal end of the marker delivery device and flared guide disposed within the tissue collection component shown in Figure 1.

[0042] Figure 24 is a longitudinal cross sectional view of the proximal end of the marker delivery device with the flared guide at the proximal end of the shaft and with the shaft deployed within the inner lumen of the tissue cutter.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0043] Figures 1-3 illustrate a biopsy system 10 embodying features of the invention which includes a disposable probe component 11, a driver component 12 and specimen collector 13.

[0044] The probe component 11 generally includes an elongated distal shaft 14 having a tubular section or cannula 15 with a tissue penetrating tip 16 on the distal end thereof and an open, tissue receiving aperture 17. The probe component 11 also includes a probe housing 18 with a housing cover 19 which is configured to interfit with the driver component 12. A tissue cutter 20 is slidably disposed within

the probe and has a distal cutting surface 21 which severs tissue which extends through the tissue receiving aperture 17.

[0045] Details of the probe component 11 are further shown in Figs 4A and 4B. The probe housing 18 has a mechanical system for rotating the housing and the tubular section 15 secured thereto to control the angular position of the tissue receiving aperture 17 and for moving the tissue cutter 20 slidably disposed within the probe component 11.

[0046] The mechanical system of the driver component 12 has first driving gear 22 that is configured to engage the probe gear 23 and rotate the probe housing 18 so as to adjust the orientation of aperture 17 in the distal extremity of the tubular section 15. The probe gear 23 is secured to the rotating connector body 24 by adhesive 25. The proximal extremity of the tubular section 15 is secured to the rotating connector body 24 by adhesive 26. An end cap 27 retains the connector body 24 within the probe housing 18. Rotation of the probe gear 23 rotates the connector body 24 and the attached tubular section 15. The rotation is preferably controlled so that the tubular section 15 rotates in discrete steps about the longitudinal axis 28 to adjust the angular orientation of the aperture 17 about the longitudinal axis. Preferably these discrete orientations may be provided in increments of 30° which can be readily indicated by arrow 29 at the distal end of the probe housing 18 as shown in Figure 8.

[0047] The second driving gear 30 is configured to drive the tissue cutter 20 longitudinally. The driving gear 30 engages probe gear 31 which drives cutter traverse nut 32 and cutter screw 33 threadably connected to the cutter traverse nut. The distal end of the cutter screw 33 is provided with a recess 34 which receives the rib 35 of the cutter shuttle 36. The cutter shuttle 36 is secured to the tissue cutter 20

by adhesive 37. The probe gear 31 is secured to the cutter traverse nut 32 by adhesive 38. Rotation of the probe gear 31 adjusts the relative axial position of the cutter screw 33 with respect to the cutter traverse nut 32 which is secured to the cutter shuttle 36. Longitudinal movement of the tissue cutter 20 follows the longitudinal movement of the cutter shuttle 36 resulting from the movement of cutter screw 33. The length of the tissue receiving aperture 17, and as a result the length of the specimen, can be controlled by adjusting the initial longitudinal position of the distal end of the tissue cutter 20 within the aperture, before cutting.

[0048] The third driving gear 40 is configured to rotate or oscillate the tissue cutter 20 as the cutter moves along the longitudinal axis 28 to facilitate the cutting action of the cutting surface 21 on the distal end of the cutter. The third driving gear 40 engages probe gear 41 which is secured to cutter oscillation shaft 42 by adhesive 43. The probe gear 41 may be oscillated back and forth about the longitudinal axis 28 or rotated continuously in a single direction about the longitudinal axis, or both depending upon the desired rotational movement of the tissue cutter.

[0049] A biased valve assembly 44 is provided in the distal end of the probe housing 18 to ensure sealing when a vacuum is developed within the interior 45 of the tissue cutter 20 while providing an atmospheric vent 46 between the interior surface 47 of the tubular section 15 and the exterior surface 48 of the tissue cutter 20. The valve assembly 44 includes a spring 49, valve body 50 and a valve collar 51 which is secured to the proximal end of the tubular section 15 by adhesive 52. The proximal end of the valve spring 49 rests against the shoulder 53 provided in the exterior of the valve body 50. A biased cutter shaft seal 54 slidably engages the exterior 48 of the tissue cutter 20.

[0050] The tissue specimen collector 13 is secured to the proximal end of the housing of probe component 11 and has an interior 55 in fluid communication with the inner lumen 56 extending within the tissue cutter 20 and has a removable proximal wall 57 of specimen receiving cartridge 58 which gives access to the interior 55 and any tissue specimens which may have been drawn therein. A vacuum is generated within the interior 55 to draw tissue specimens through the inner lumen 45 into the interior 55. Tubular member 59 has a distal end which is in fluid communication with the interior 55 of the tissue specimen collector 13 and has a proximal end (not shown) which is configured to be connected to a vacuum source. Application of a vacuum within the tubular member 59 aids in pulling tissue into the interior 17 of the tubular section 15 and transfer of the severed tissue specimen through the inner lumen 45 of the tissue cutter 20 to the specimen cartridge 58.

[0051] The driver 12 has a housing 60 with an upper concave surface 61 which is configured to receive the lower surface 62 of the probe housing 18. Three partially exposed driving gears 22, 30 and 40 are provided on the proximal end of the driver 12 which are configured to engage the probe gears 23, 31 and 41 respectively. The drive 12 is provided with three separately operating drive motors (not shown) which drive the drive gears 22, 30 and 40. The separate drive motors (not shown) are connected to and the operation thereof controlled by a control module, such as described in copending application Serial No. 10/847,699, filed on May 17, 2004. The control module controls the motors which move the individual drive gears 22, 30 and 40. The gear 22 engages gear 23 in the probe 11 to control the rotation of the probe housing 18 and the location and orientation of the tissue receiving aperture 17. The drive gear 30 engages probe gear 31 to control the longitudinal position and motion of the tissue cutter 20 along the longitudinal axis 28. Drive gear 40 engages

probe gear 41 to control the oscillation or rotation of the tissue cutter 20 about the longitudinal axis 28.

[0052] As shown in Figure 7, the front face of the driver component 12 is provided with light sources 66 and 67 and a manually activatable switch 68 to activate the light sources and enable the physician and other operating personnel to better view the operating site on the patient. Other manual switches, e.g. a foot activated switch, may be employed. Alternatively, the light sources may be automatically activated when the probe component 11 is installed on the driver 12 or other events such as when electrical power is turned on. The driver component 12 may have a battery pack for the light sources 66 and 67.

[0053] The tissue penetrating distal tip 16 may have a variety of tip shapes. A particularly suitable distal tip embodying features of the invention is shown in Figures 9-20. The tissue penetrating distal tip generally includes a base 70, a sharp distal point 71, a first concave surface 72, a second concave surface 73 and a third concave surface 74.

[0054] The intersection between the first concave surface 72 and the second concave surface 73 forms the first curved cutting edge 75. The intersection between the second concave surface 73 and the third concave surface 74 forms the second curved cutting edge 76. The intersection between the third concave surface and the first concave surface 72 forms the third curved cutting surface 77.

[0055] The concave surfaces 72, 73 and 74 are hollow ground and the pentrating tip 16 is then electro-polished to increase the sharpness of the cutting edges 75, 76 and 77. The penetrating distal tip 16 may be formed of suitable surgical stainless steel such as 17-4 stainless steel. Other materials may be suitable. The penetrating distal tip 16 is preferably electro-polished in an acidic solution to sharpen the curved

cutting edges and thereby facilitate tissue penetration. Suitable electro-polishing solutions include Electro Glo sold by the Electro Glo Distributing Co.

[0056] The base 70 of the tissue penetrating tip 16 may be secured to the distal end of the elongated shaft of the biopsy device 10 for accessing and collecting tissue from a target site within a patient. The sharp distal tip 16 embodying features of the invention readily penetrates a patient's tissue, particularly breast tissue and facilitates guiding the distal end of the biopsy or other device to a desired intracorporeal location.

[0057] The tissue penetrating tips may also be employed on biopsy devices such as those described in co-pending application Serial No. 10/642,,406, filed on August 15, 2003, which is assigned to the present assignee. Alternatively, the distal tip may be provided with an arcuate RF electrode such as disclosed in U.S. Patent No. 6,261,241, and U.S. Patent No. 6,471,700, both assigned to the present assignee.

[0058] The separate driver component 12 allows the probe unit 11 to be disposable. The drive gears of the drive component 12 control the motion of the tissue cutting member 20 for cutting and the motion of the tubular section 15 to orient the aperture 17. Other means (not shown) may provide mechanical and electrical power, vacuum, and control to the probe device. Examples of replaceable snap-in type probe units are disclosed in Burbank et al., U.S. Patent Application 10/179,933, "Apparatus and Methods for Accessing a Body Site". Drive units such as that described in WO 02/069808 (which corresponds to co-pending U.S. application Serial No. 09/707,022, filed November 6, 2000 and U.S. application Serial No. 09/864,021, filed May 23, 2001), which are assigned to the present assignee, may be readily modified by those skilled in the art to accommodate the movement of the cutting member 20.

[0059] In use, the distal end of the probe component 11 is advanced within the patient with the tissue cutter 20 in a forward or closed position (Fig. 4B), until the aperture 17 of the tubular section 15 is located in a desired location for taking a tissue specimen. The tissue cutter 20 is then withdrawn proximally to an open position to open the aperture 17. The withdrawal of the tissue cutter can be used to control the length of the aperture which is opened in order to control the length of the specimen which is severed. A vacuum is applied to the interior 45 of the tissue cutter 20 to draw tissue at the site into the inner lumen of the tubular section 15 through the aperture 17. The tissue cutter 20 is then driven distally by rotation of probe gear 30 and rotated or oscillated by drive gear 40 engaging probe gear 41 to sever the aspirated tissue from the supporting tissue at the target site with the tissue cutting surface 21. The vacuum within the interior of the tissue cutter 20 causes the tissue specimen to be drawn through the inner lumen 45 of the tissue cutter 20 and into the cartridge 58 of specimen collector 13 shown in Fig. 2. Positive pressure or even ambient conditions distal to the tissue specimen can facilitate tissue passing through the interior 45 of tissue cutter 20. If another tissue specimen is desired, the tubular section 15 may be rotated by the drive gear 22 engaging the probe gear 23 in one or more steps to repeat obtaining another tissue specimen in the same manner without otherwise moving the probe component 11. Typically, a first tissue specimen is obtained with the aperture 17 of the probe 11 in the 12 o-clock position, the second at the 3 o-clock position, the third at the 9 o-clock position and the fourth at the 6 o-clock position. The location of the second and third specimens may be reversed. The position of the aperture 17 may be indicated by a marker arrow 29 at the end cap 27 so that the physician or other operating personnel can readily determine what the orientation of the aperture 17 within the patient.

[0060] The biopsy system 10 may be hand held for some biopsy procedures or the system may be mounted on a stereotactic mounting stage 80 as shown in Figure 21. A shoe 81 is slidably mounted to a rail 82 of a Fisher stage. The mounting member 83 is secured to the shoe 81 by a threaded post (not shown) secured to thumbwheel 84. As shown in Figure 10, the bottom surface 85 of the driver component 12 is configured to conform at least in part to the upper surface of the mounting member 83. The sampling and vacuum switches 86 and 87 respectively on the driver component 12 are actuated by the optional sampling and vacuum actuating elements 88 and 89 on the mounting member 83. Alternatively, sampling and vacuum may be actuated with a foot pedal. As shown in Figure 22, the driver component has an operator dial 90 which when turned opens a threaded hole 91 for receiving a threaded post (not shown) secured to the thumbwheel 84 and the locating pin holes 92 and 93 which receive the complementary posts (not shown) in the mounting member 83.

[0061] As mentioned above, positive pressure or even ambient conditions will aid in passing the severed tissue specimen through the inner lumen 45 of tissue cutter 20 into the cartridge 58 of specimen collector 13. As shown in Figures 4A and 4B venting valve can provide ambient pressure behind the tissue specimen in the cutter interior 45 from the interior of the tubular section 15. The valve body 50 is opened for atmospheric venting when the tissue cutter 20 is in the forward position upon the completion of severing the specimen from the tissue site. However, when the tissue cutter 20 is pulled back proximally the valve spring 49 urges the valve body 50 back to a closed position. While the tissue cutter 20 is shown with a tissue cutting surface 21 which is perpendicular to the longitudinal axis 28, the tissue cutting surface may

be at an angle or even parallel to the longitudinal axis as described in co-pending application Serial No. 10/642,406, filed August 15, 2003.

[0062] The distal cutting edge 21 of the tissue cutter 20 may initially be located proximal to the aperture 17 to provide a full aperture for receiving tissue or it can be initially located within the aperture 17 in order to control the length of the specimen. The cutting action of tissue cutter 20 preferably continues until the beveled cutting surface 21 has completely traversed the aperture 17 to ensure that the tissue drawn through the aperture is completely severed from supporting tissue at the biopsy site. A vacuum may be applied to aspirate the severed tissue specimen through the inner lumen of the tissue cutter 20 to the cartridge in the specimen collector at the proximal end of the biopsy device. Positive pressure or access to ambient conditions may be provided in the distal end of the tubular section to aid in the specimen transfer.

[0063] After the removable wall 57 of the specimen receiving cartridge 58 is removed and the specimens therein removed, it is frequently desirable to deliver one or more markers to the target site from which the specimens have been removed. Such marker delivery devices are shown in co-pending application Serial No. 10/753,694, filed on January 7, 2004 and co-pending application Serial No. 10/444,770, filed May 23, 2003. However, the distal ends of these marker delivery devices are very small and they can be difficult to insert into the proximal end of the tissue cutter 20 which is just slightly larger to accommodate the marker delivery shaft.

[0064] Figure 22 illustrates a marker delivery device 100 which is particularly suitable to facilitate the introduction of the distal end of the shaft 101 into the inner lumen 45 of the tissue cutter 20 and the advancement therein. As shown in Figure

23, to facilitate the insertion of the small diameter distal tip 101 of the marker delivery device 100 into the slightly larger inner lumen 45 of the tubular cutter 20 at its proximal end, the distal tip is preferably provided with an outwardly flared guide 102 which is slidably mounted on the shaft 103 of the marker delivery device 100. The proximal end of the tubular cutter 20, the flared guide 102 and/or the distal tip 101 may be provided with mating guide elements which orient the marker delivery device with the cannula 15 of the biopsy device. To ensure that one or more markers are discharged through the aperture 17 of the biopsy device 10 when the pusher element slidably disposed within the delivery device is urged distally to press at least one marker body out the discharge opening in the distal portion of the elongated shaft of the marker delivery device. As indicated in Figure 23, the shaft 103 of the marker delivery device 100 is advanced into the inner lumen 45 of the tissue cutter 20 so that the distal end 101 of the marker delivery device 100 is adjacent to the aperture 17 of the cannula 15. Plunger 104 is pressed further into the inner lumen of shaft 103 to eject one or more markers 105 through the aperture 17 in the tubular section 15 before the biopsy device 10 is removed from the patient. The delivery of markers to the target site after specimen removal, while the distal end of the biopsy device is still at the biopsy site, ensures that the markers are properly position at the biopsy site.

[0065] While the slidably mounted, flared proximal guide 102 is described with respect to being disposed on the shaft 103 of marker delivery device 101, the flared guide 102 has wide application within a variety of biopsy and other devices where one small diameter tubular member is to be inserted into a slightly larger, but still small diameter second tubular member.

[0066] The elongated probe component 11 of the biopsy system 10 has a length of about 3 to about 20 cm, preferably, about 5 to about 13 cm, and more specifically, about 8 to about 9 cm for breast biopsy use. To assist in properly locating the probe 11 during advancement thereof into a patient's body, the distal extremity of the tubular section may be provided with a marker at a desirable location that provide enhanced visualization by eye, by ultrasound, by X-ray, MRI or other imaging or visualization means. Manual palpation may also be employed. An echogenic polymer coating that increases contrast resolution in ultrasound imaging devices (such as ECHOCOAT™ by STS Biopolymers, of Henrietta, NY) is suitable for ultrasonic visualization. Radiopaque markers may be made with, for example, stainless steel, platinum, gold, iridium, tantalum, tungsten, silver, rhodium, nickel, bismuth, other radiopaque metals, alloys and oxides of these metals. In addition, the surfaces of the device in contact with tissue or other components of the device may be provided with a suitable lubricious coating such as a hydrophilic material or a fluoropolymer.

[0067] The tubular section and the tissue cutter are preferably formed of a surgical grade stainless steel. However, other high strength materials such as MP35N, other cobalt-chromium alloys, NiTi alloys, ceramics, glasses, and high strength polymeric materials or combinations thereof may be suitable.

[0068] A patient's skin usually must be breached in order to gain access to a body site where a tissue specimen is to be obtained. A scalpel or other surgical instrument may be used to make an initial incision in the skin. After the specimens have been taken, the biopsy device may be removed from the patient. The entire device may be removed; however, in some embodiments, the cartridge 58 may be removed from the system 10 and a delivery cannula may be inserted through the

inner lumen of the cutter 20 to deliver markers to the biopsy site through the aperture 17. In addition, it will be readily appreciated that other types of instruments may be inserted into the tissue site through the tissue cutter in addition to or in place of the instruments described above. Moreover, therapeutic or diagnostic agents may be delivered through the tissue cutter 20 or the tubular section 15.

[0069] While particular forms of the invention have been illustrated and described herein, it will be apparent that various modifications and improvements can be made to the invention. For example, while the various embodiments of the invention have been described herein in terms of a biopsy device, it should be apparent that the devices and methods of utilizing the device may be employed to remove tissue for purposes other than for biopsy, i.e. for treatment or other diagnoses. Additionally, the tissue penetrating distal tip design may be employed on probes for other uses. Other modifications include, for example, a tissue cutter slidably mounted around the tubular section of the probe component rather than within the tubular section. Moreover, individual features of embodiments of the invention may be shown in some drawings and not in others, but those skilled in the art will recognize that individual features of one embodiment of the invention can be combined with any or all the features of another embodiment. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated.

[0070] Terms such a "element", "member", "device", "section", "portion", "means", "step" and words of similar import, when used in the following claims, shall not be construed as invoking the provisions of 35 U.S.C. §112(6) unless the claims expressly use the term "means" followed by a particular function without specific structure or the term "step" or "steps" followed by a particular function without

specific action. All patents and patent applications referred herein are incorporated by reference in their entirety.

WHAT IS CLAIMED IS:

1. A tissue biopsy system for accessing and collecting one or more tissue specimens from a target site within a patient, comprising:

a. a disposable elongated probe component comprising

i. a distal shaft portion with a penetrating distal tip, a tubular section proximal to the distal tip, an inner lumen extending within the tubular section and an open, tissue receiving aperture in the tubular section which provides access to tissue at the targeted site, a proximal extremity configured to be secured to a driver unit, and

ii. an elongated tissue cutting member which is disposed within the tubular section, which has at least one tissue cutting edge and which has an inner lumen extending therein; and

b. a driver component which is configured to receive a proximal portion of the probe component in an operational relationship, which has a first driver motor configured to rotate the tubular section of the probe component to orient the tissue receiving aperture in the distal end of the tubular section and which has a second driver motor configured to drive the tissue cutting member longitudinally within the tubular section to cut tissue extending into the tubular section through the tissue receiving aperture thereof.

2. The system of claim 1 wherein the driver component has a third driver motor configured to rotate the tissue cutting member within the tubular section.

3. The system of claim 2 wherein the third driver motor rotates the tissue cutting member within the tubular section as the tissue cutting member moves longitudinally therein.

4. The system of claim 1 wherein the driver component has a third driver motor configured to oscillate the tissue cutting member within the tubular section.

5. The system of claim 4 wherein the third driver motor oscillates the tissue cutting member within the tubular section as the tissue cutting member moves longitudinally therein.

6. The system of claim 1 including a vacuum source connected in fluid communication with the inner lumen of the tissue cutting member to withdraw tissue therethrough.

7. The system of claim 6 wherein a tissue collector is in fluid communication with the inner lumen of the tissue cutting member configured to receive tissue withdrawn through the tissue cutting member.

8. The system of claim 7 wherein the tissue collector is located between the tissue cutting member and the vacuum source.

9. The system of claim 1 wherein the first driving motor is configured to rotate the tubular section in discrete steps about the longitudinal axis thereof.

10 The system of claim 9 wherein the first driving motor is configured to rotate the tubular section in increments of about 15° to about 45°.

11. The system of claim 9 wherein the first driving motor is configured to rotate the tubular section in increments of about 30°.

12. The system of claim 1 wherein the distal extremity of the tubular section of the probe component has a circular transverse cross-section.

13. The system of claim 1 including a protective tube which has proximal and distal ends, which has an inner lumen extending therein, which is disposed about the tubular section.

14. The system of claim 13 wherein the protective tube has multiple longitudinally oriented lobes.

15. The system of claim 1 wherein the driver component has at least one illuminating element in a distal portion thereof.

16. The system of claim 15 wherein the at least one illuminating element is a light emitting diode.

17. The system of claim 15 wherein the driver component has two illuminating elements.

18. The system of claim 15 wherein the at least one illuminating element has a manually operable switch.

19. The system of claim 18 wherein the manually operable switch is located in the distal end of the driver component.

20. The system of claim 1 wherein at least one of the driving motors are electrically powered.

21. The system of claim 1 wherein at least one of the driving motors are hydraulically powered.

22. The system of claim 1 wherein at least one of the driving motors are pneumatically powered.

23. The system of claim 1 including a control module which has an electrical source and a vacuum source.

24. The system of claim 23 wherein the control module controls the rotation of the tubular section.

25. The biopsy system of claim 1 wherein the driver component is configured for mounting onto a stereotactic stage of a mammography system.

26. The biopsy system of claim 1 wherein the penetrating distal tip has a proximal base configured to be secured to a probe shaft; a sharp distal point distal to the proximal base, a first concave surface, a second concave surface which intersects the first concave surface forming therewith a curved cutting edge that leads to the sharp distal point, and a third concave surface which intersects the first concave surface forming therewith a second curved cutting edge leading to the sharp distal point and which intersects the second concave surface forming therewith a third curved cutting edge that leads to the sharp distal point.

27. The probe end of claim 26 wherein the surface of the probe tip is electro-polished in an acid solution.

28. The probe end of claim 26 wherein the concave surfaces have center lines which extend from the base to the sharp distal point.

29. The probe end of claim 26 wherein the concave surfaces are equi-spaced about a longitudinal axis of the probe tip.

30. The probe end of claim 26 wherein the concave surfaces have essentially the same area.

31. The probe end of claim 26 wherein the concave surfaces have essentially the same concavity.

32. A tissue biopsy system for accessing and collecting one or more tissue specimens from a target site within a patient, comprising:

a. a disposable elongated probe component comprising

i. an elongated tubular section which has a longitudinal axis, which has an inner lumen extending therein, which has a tissue penetrating distal tip and which has an aperture proximal to the penetrating distal tip configured to receive tissue from the target site, and

ii. an elongated tissue cutting member which is disposed within the elongated tubular section, which has at least one tissue cutting edge, which has an inner lumen extending therein and which is configured to cut a tissue specimen from tissue extending into the tissue receiving aperture of the elongated tubular member;

b. a driver component which is configured to receive a proximal portion of the probe component in an operational relationship, which has a first driver motor configured to rotate the tubular section of the probe component to orient the tissue receiving aperture in the distal end of the tubular section, which has a second driver motor configured to drive the tissue cutting member longitudinally within the tubular section of the probe to cut a tissue specimen from tissue extending into the tissue receiving aperture of the elongated tubular member; and

c. at least one light source in a distal portion of the driver component for illuminating an operation site.

33. The biopsy system of claim 32 wherein the driver component is configured for mounting onto a stereotactic stage of a mammography system.

34. The biopsy system of claim 32 wherein the driver component has a third driving motor configured to rotate the tissue cutting member.

35. The biopsy system of claim 34 wherein the third driving motor is configured to rotate the tissue cutting member as the member is moved longitudinally within the tubular section.

36. The system of claim 32 wherein the at least one illuminating element is a light emitting diode.

37. The system of claim 32 wherein the driver component has two illuminating elements.

38. The system of claim 32 wherein the at least one illuminating elements has a manually operable switch.

39. The system of claim 38 wherein the manually operable switch is located in the distal end of the driver component.

40. The system of claim 32 including a vacuum source connected in fluid communication with the inner lumen of the tissue cutting member.

41. The system of claim 38 wherein a tissue collector is in fluid communication with the inner lumen of the tissue cutting member.

42. The system of claim 41 wherein the tissue collector is located between the tissue cutting member and the vacuum source.

43. A tissue biopsy probe device for accessing one or more tissue specimens from a target site within a patient, comprising:

a. an elongated tubular section which has a longitudinal axis, which has an inner lumen extending therein, which has a distal tip and which has an aperture proximal to the distal tip configured to receive tissue from the target site, and

b. an elongated tissue cutting member which is slidably disposed within the elongated tubular section, which has a distal end with at least one tissue cutting edge, which has an inner lumen extending therein and which is configured for longitudinal movement within the tubular section; and

c. a proximal housing which contains a proximal portion of the elongated tissue cutting member, a driving shuttle secured to the proximal portion of the elongated tissue cutting member and a first drive member engaging the shuttle to move the elongated tissue cutting member and a second drive member secured to a proximal portion of the tubular section within the housing configured to rotate the tubular section about its longitudinal axis.

44. The tissue biopsy probe device of claim 48 wherein the first drive member has first and second interfitting tubular drive elements with the first tubular drive element having a threaded interior and with the second tubular drive element having a threaded exterior configured to engage the threaded interior of the first tubular drive element.

45. The tissue biopsy probe device of claim 49 wherein the first tubular drive element is configured to be rotated and the second tubular drive element is fixed to the tissue cutting member.

46. The tissue biopsy probe device of claim 50 wherein the second tubular drive element is fixed to the driving shuttle.

47. The tissue biopsy probe device of claim 50 wherein a marker element is secured to the tubular section adjacent the distal face of the probe housing to indicate the orientation of the aperture in the tubular section.

48. A tissue biopsy system for collecting one or more tissue specimens from a target site within a patient, comprising:

a. a disposable elongated probe component comprising

i. a distal shaft portion with a penetrating distal tip, a tubular section proximal to the distal tip, an inner lumen extending within the tubular section and an open, tissue receiving aperture in the tubular section which provides access to tissue at the targeted site, a proximal extremity configured to be secured to a driver unit, and

ii. an elongated tissue cutting member which is disposed about the tubular section, which has at least one tissue cutting edge and which has an inner lumen extending therein; and

b. a driver component which is configured to receive a proximal portion of the probe component in an operational relationship, which has a first driver motor configured to rotate the tubular section of the probe component to orient the tissue receiving aperture in the distal end of the tubular section and which has a second driver motor configured to drive the tissue cutting member longitudinally to cut tissue extending into the tubular section through the tissue receiving aperture thereof.

49. The system of claim 53 wherein the driver component has a third driver motor configured to rotate the tissue cutting member.

50. The system of claim 54 wherein the third driver motor rotates the tissue cutting member as the tissue cutting member moves longitudinally.

51. The system of claim 53 wherein the driver component has a third driver motor configured to oscillate the tissue cutting member.

52. The system of claim 56 wherein the third driver motor oscillates the tissue cutting member as the tissue cutting member moves longitudinally.

53. The system of claim 53 including a vacuum source connected in fluid communication with the inner lumen of the tubular section of the probe component to withdraw tissue therethrough.

54. A tissue biopsy system for collecting one or more tissue specimens from a target site within a patient, comprising:

a. a disposable elongated probe component comprising

i. a distal shaft portion with a penetrating distal tip, a tubular section proximal to the distal tip, an inner lumen extending within the tubular section and an open, tissue receiving aperture in the tubular section which provides access to tissue at the targeted site and a proximal extremity configured to be secured to a driver unit, and

ii. an elongated tissue cutting member which is disposed about the tubular section, which has at least one tissue cutting edge, which has an inner lumen extending therein and which has a proximal end configured to receive a distal tip of a marker delivery device with a flared guide to guide the distal tip into the proximal end of the tissue cutting member; and

b. a driver component which is configured to receive a proximal portion of the probe component in an operational relationship, which has a first driver motor configured to rotate the tubular section of the probe component to orient the tissue receiving aperture in the distal end of the tubular section and which has a second driver motor configured to drive the tissue cutting member longitudinally to cut tissue extending through the tissue receiving aperture thereof.

55. A device for delivery of one or more marker bodies through a tubular member of a biopsy device, comprising:

a. an elongated shaft having an inner lumen and a discharge opening in a distal portion of the elongated shaft;

b. at least one marker body which is disposed within the inner lumen of the elongated shaft;

c. a pusher element which is slidably disposed within the delivery device and which is configured to urge at least one marker body out the discharge opening in the distal portion of the elongated shaft; and

d. a distally flared guide member which is disposed on the elongated shaft and which is configured to guide the distal portion of the elongated shaft into a proximal end of a tubular member of a biopsy device.

56. A tissue biopsy system for collecting at least one tissue specimen from a target site within a patient and delivering at least one marker to the target site after the at least one tissue specimen has been removed from the site, comprising:

a. a disposable elongated probe component comprising

i. a distal shaft portion with a penetrating distal tip, a tubular section proximal to the distal tip, an inner lumen extending within the tubular section and an open, tissue receiving aperture in the tubular section which provides access to tissue at the targeted site, and a proximal extremity configured to be secured to a driver unit, and

ii. an elongated tubular tissue cutting member which has at least one tissue cutting edge at a distal end, which has an opening at a proximal end and which has an inner lumen extending therein to the opening in the proximal end;

b. a driver component which is configured to receive a proximal portion of the probe component in an operational relationship, which [has a first driver motor] is configured to rotate the tubular section of the probe component to orient the tissue receiving aperture in the distal end of the tubular section and which [has a second driver motor] is configured to drive the tissue cutting member longitudinally to cut tissue extending into the tubular section through the tissue receiving aperture thereof; and

c. a marker delivery component for delivery of at least one marker bodies through the tubular tissue cutting member, including:

i. an elongated shaft which has an inner lumen, a discharge opening in a distal portion of the elongated shaft and an outer diameter smaller than the inner diameter of the tubular tissue cutting member of the probe component;

ii. at least one marker body which is disposed within the inner lumen of the elongated shaft;

iii. a pusher element which is slidably disposed within the delivery device and which is configured to urge at least one marker body out the discharge opening in the distal portion of the elongated shaft; and

iv. a distally flared guide member which is disposed on the elongated shaft, which has a distal diameter much greater than the outer diameter of the proximal end of the tubular tissue cutting member and which is configured to guide the distal portion of the elongated shaft into the proximal end of the tubular cutting member.

57. A tissue penetrating probe end, comprising:

a. a proximal base configured to be secured to a probe shaft;

b. a sharp distal point distal to the proximal base;

c. a first concave surface;

b. a second concave surface which intersects the first concave surface forming therewith a curved cutting edge that leads to the sharp distal point; and

c. a third concave surface which intersects the first concave surface forming therewith a second curved cutting edge leading to the sharp distal point and which intersects the second concave surface forming therewith a third curved cutting edge that leads to the sharp distal point.

58. The probe end of claim 63 wherein the surface of the probe tip is electro-polished in an acid solution.

59. The probe end of claim 63 wherein the concave surfaces have center lines which extend from the base to the sharp distal point.

60. The probe end of claim 63 wherein the concave surfaces are equi-spaced about a longitudinal axis of the probe tip.

61. The probe end of claim 63 wherein the concave surfaces have essentially the same area.

62. The probe end of claim 63 wherein the concave surfaces have essentially the same concavity.

63. A device for accessing and collecting tissue from a target site within a patient, comprising:

a. an elongated probe which has a longitudinal axis, which has a proximal end configured to be secured to a drive, which has an inner lumen extending therein, which has a distal end and which has an aperture proximal to the distal end configured to receive tissue from the target site;

b. a tissue penetrating tip on the distal end which has

i. a proximal base secured to the distal end of the elongated probe,

ii. a sharp distal point distal to a proximal base,

iii. a first concave surface having a center line extending from the base to the sharp distal point,

iv. a second concave surface which has a center line extending from the base to the sharp distal point and which intersects the

first concave surface forming therewith a first curved cutting edge that leads to the sharp distal point, and

v. a third concave surface which has a center line extending from the base to the sharp distal point and which intersects the first concave surface forming therewith a second curved cutting edge leading to the sharp distal point and which intersects the second concave surface forming therewith a third curved cutting edge that leads to the sharp distal point; and

c. a tissue cutting means which is disposed within the elongated probe member and which is configured to cut a tissue specimen from tissue extending into the tissue receiving aperture of the elongated probe.

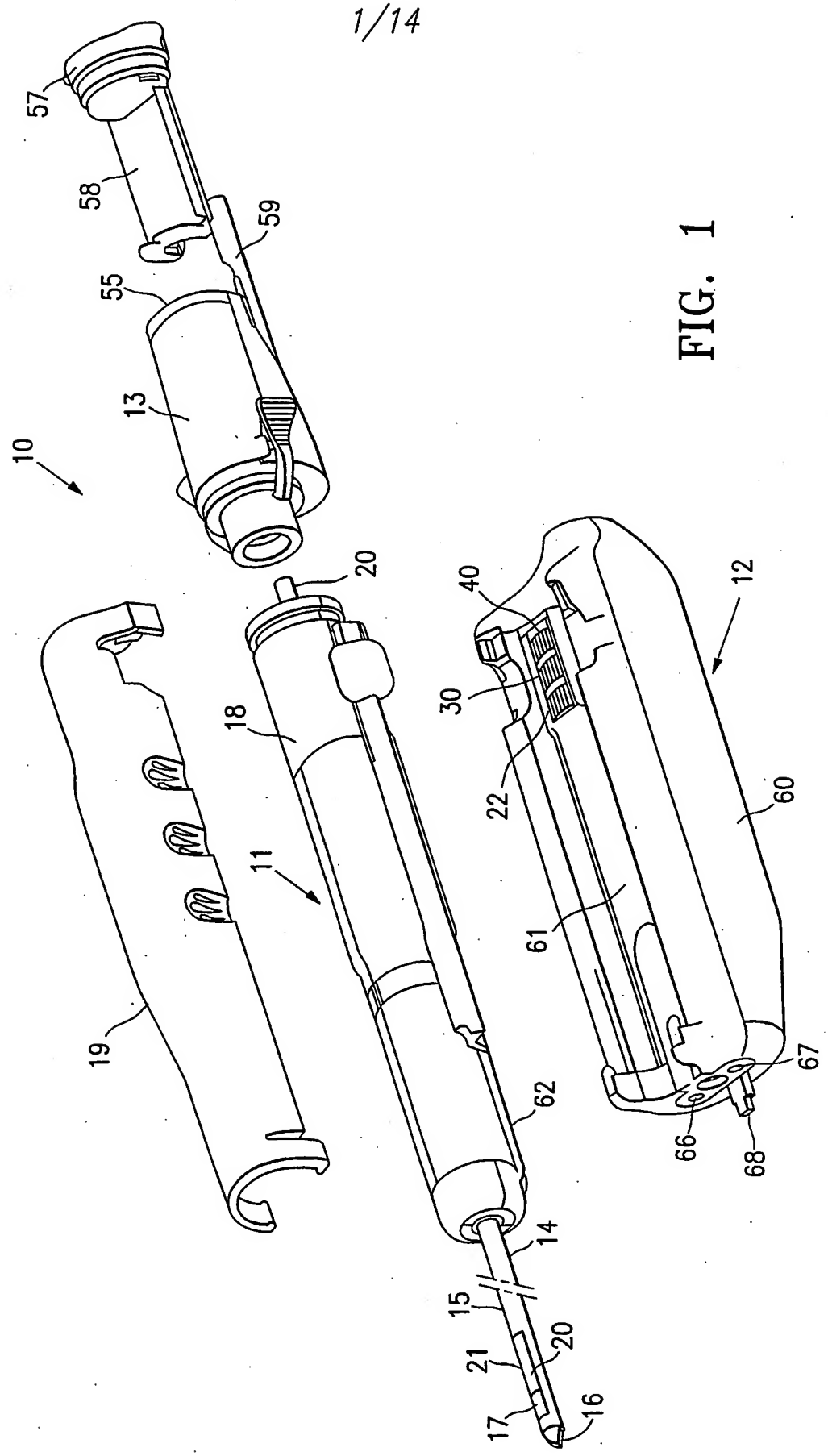

57
58
59
55
13
10
20
40
12
30
18
22
60
11
61
19
62
67
66
68
14
15
21
20
17
16

FIG. 1

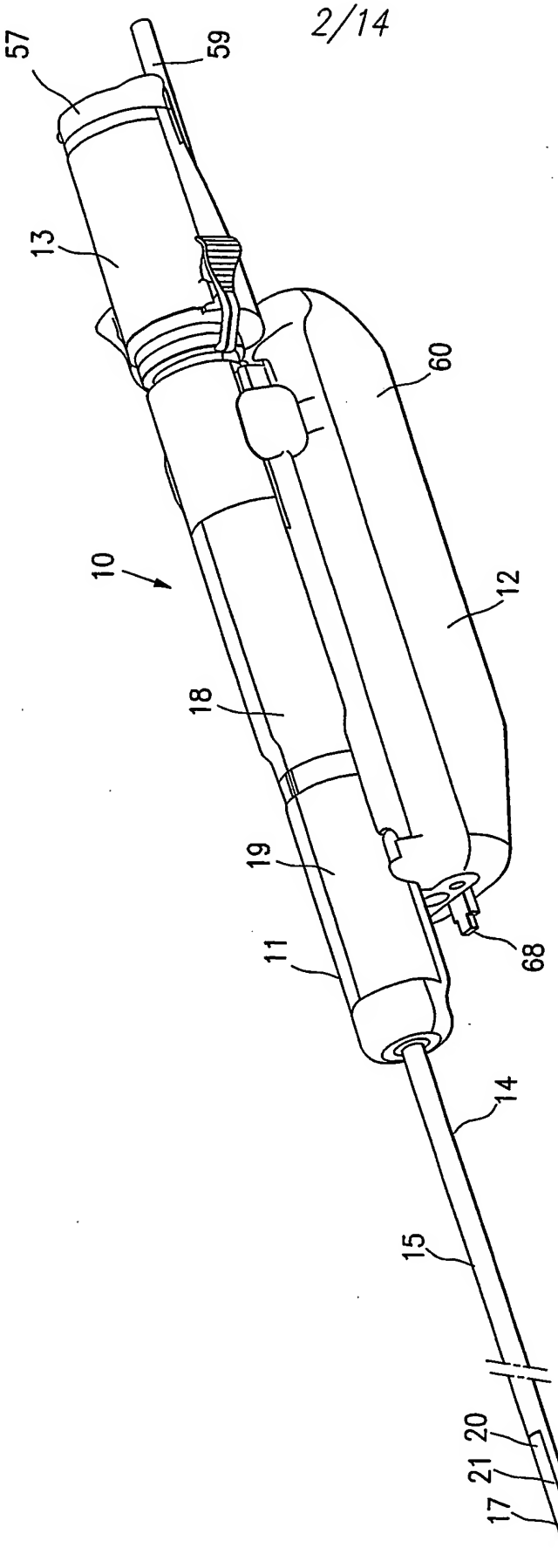


FIG. 2

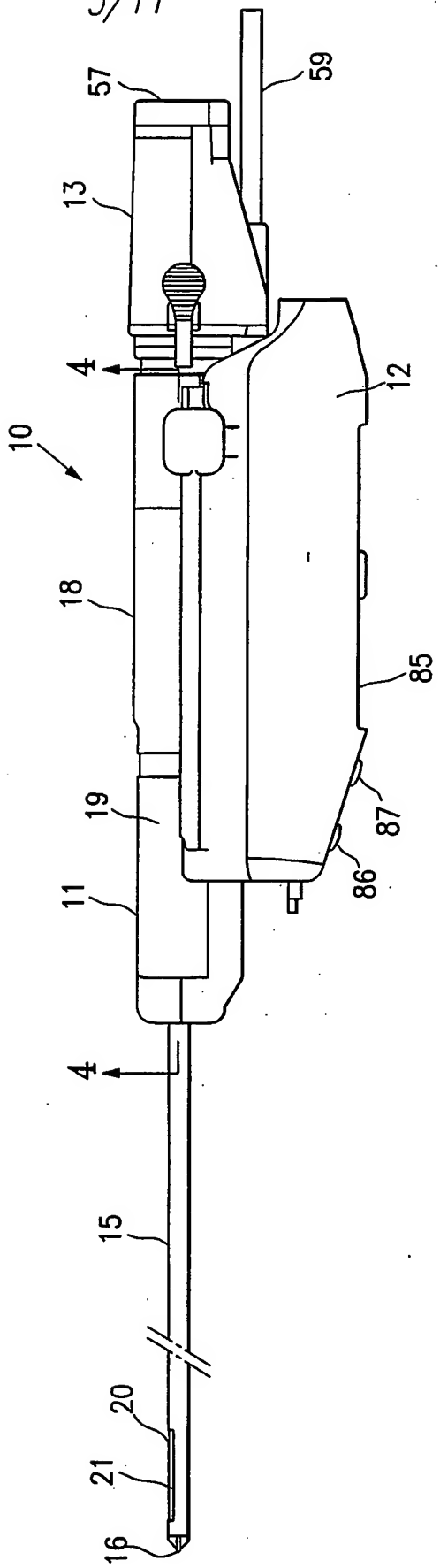


FIG. 3

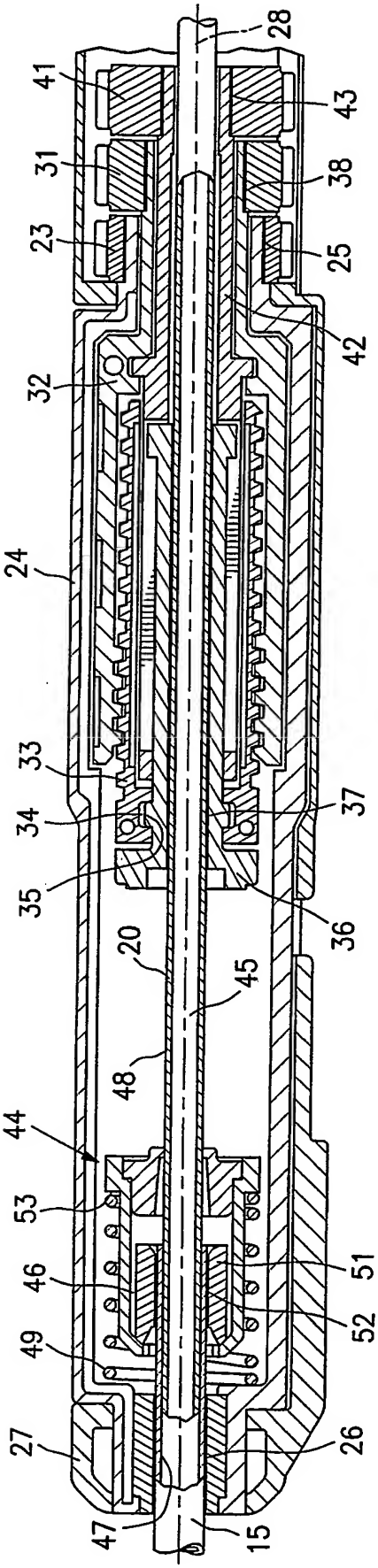

28
41
43
31
38
23
25
42
32
24
33
34
37
35
36
20
45
48
44
53
46
51
52
49
27
26
47
15

FIG. 4A

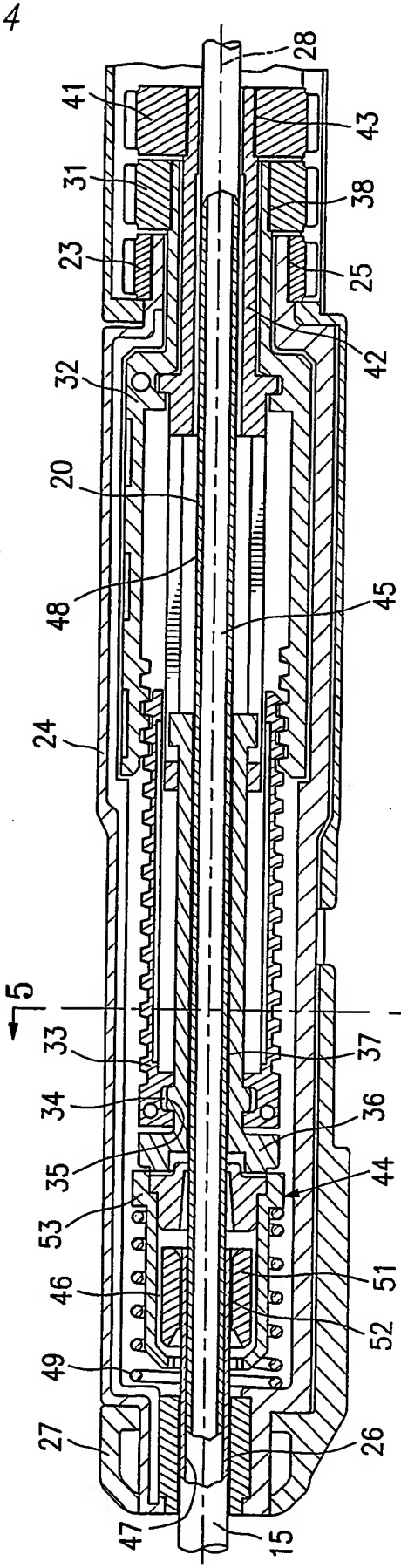

28
41
43
31
38
23
25
42
32
20
48
45
24
5
5
33
37
34
36
35
44
53
46
51
52
49
27
26
47
15

FIG. 4B

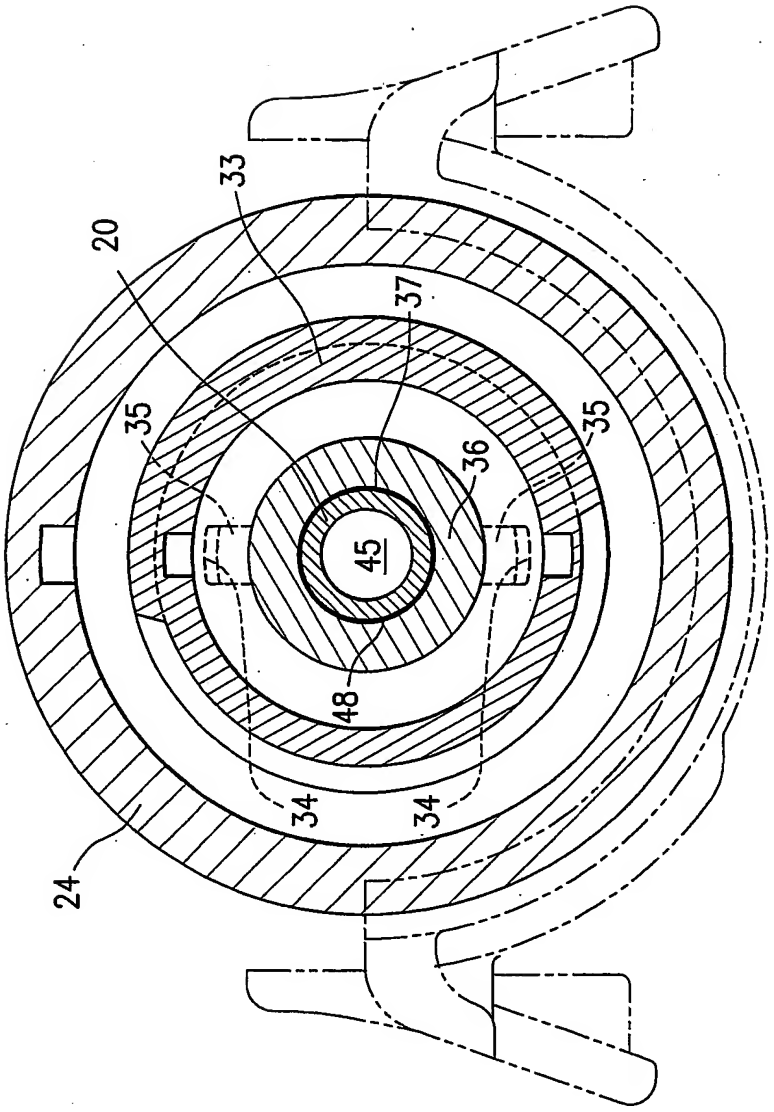


FIG. 5

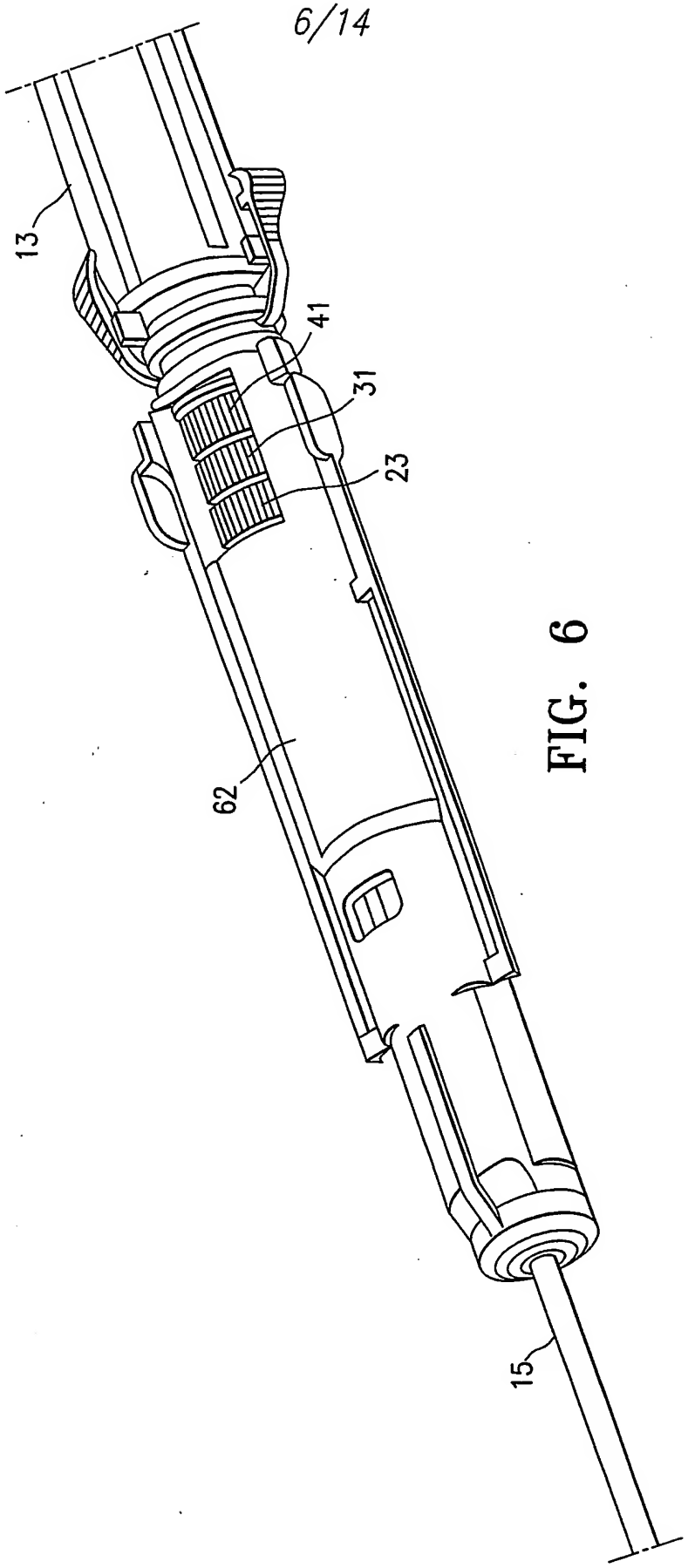


FIG. 6

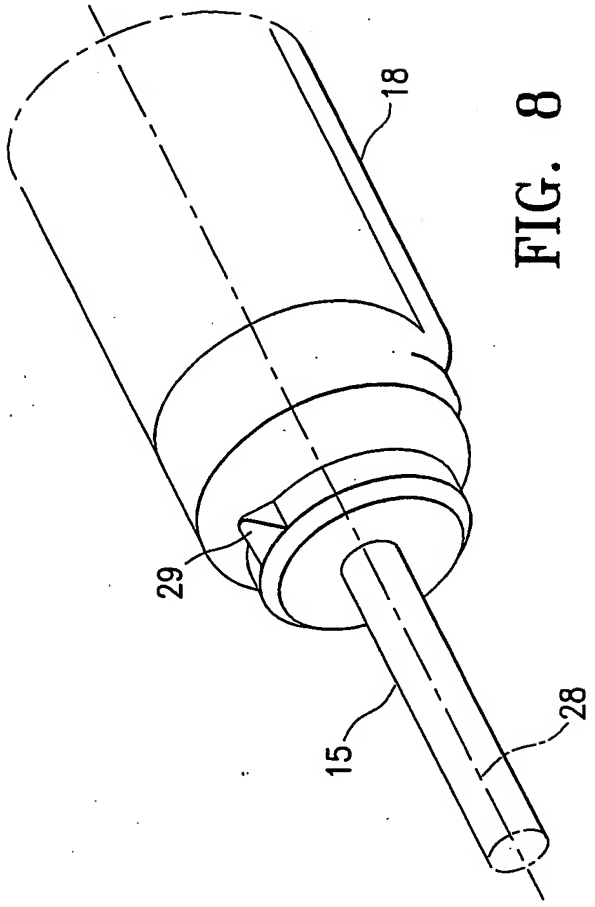


FIG. 8

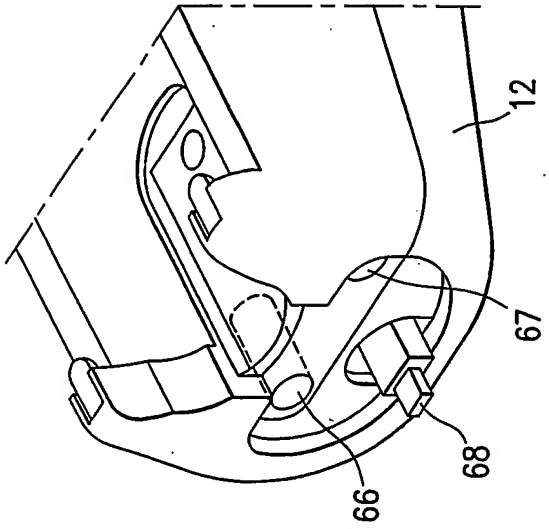


FIG. 7

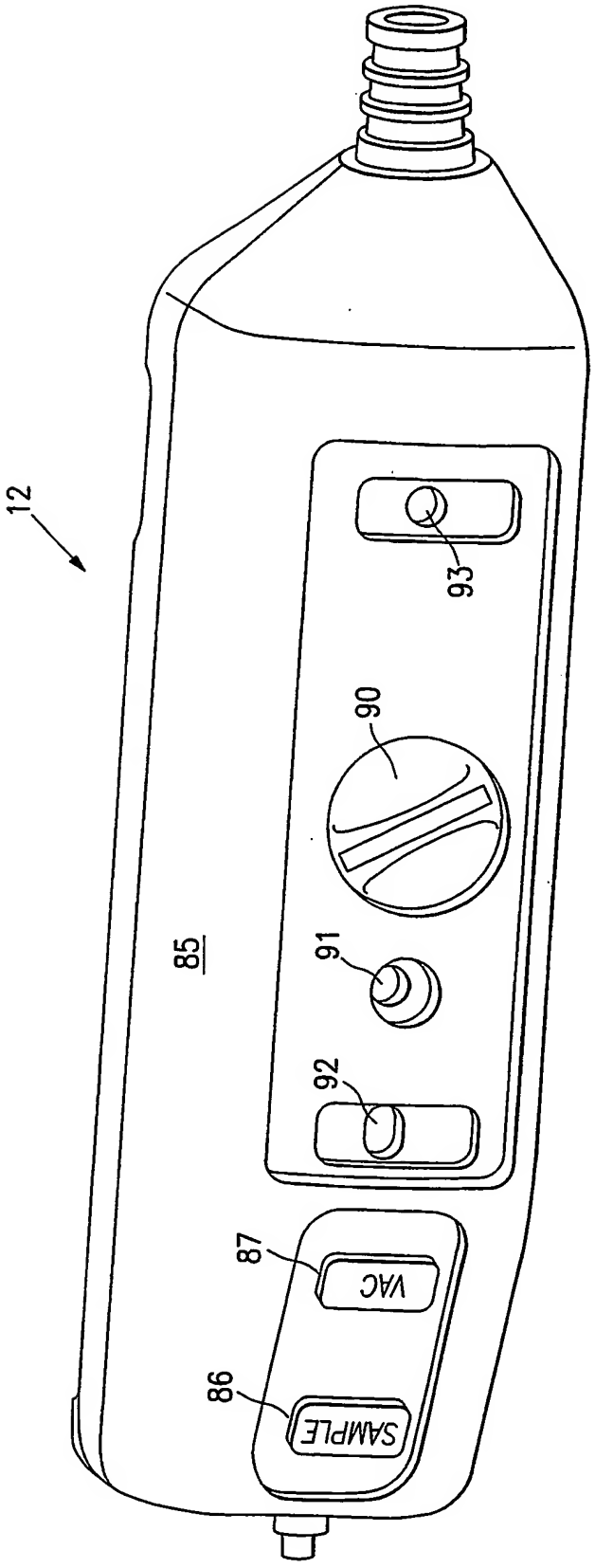


FIG. 9

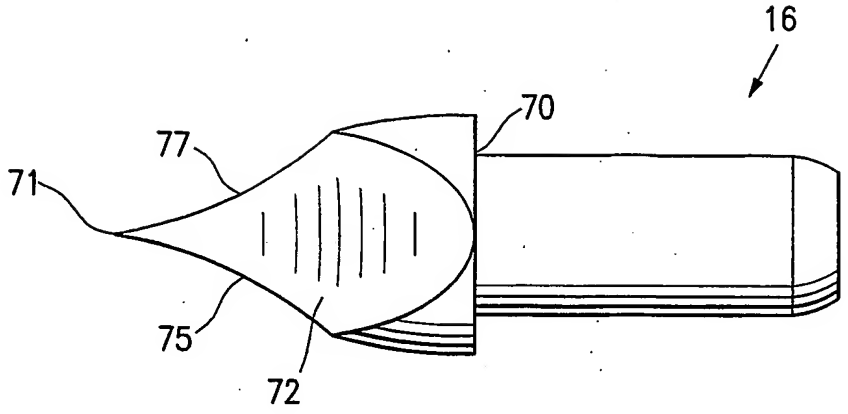


FIG. 10

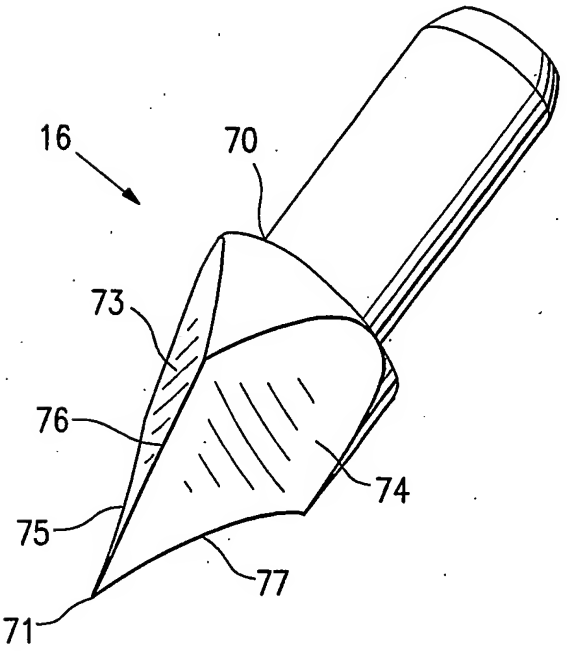


FIG. 11

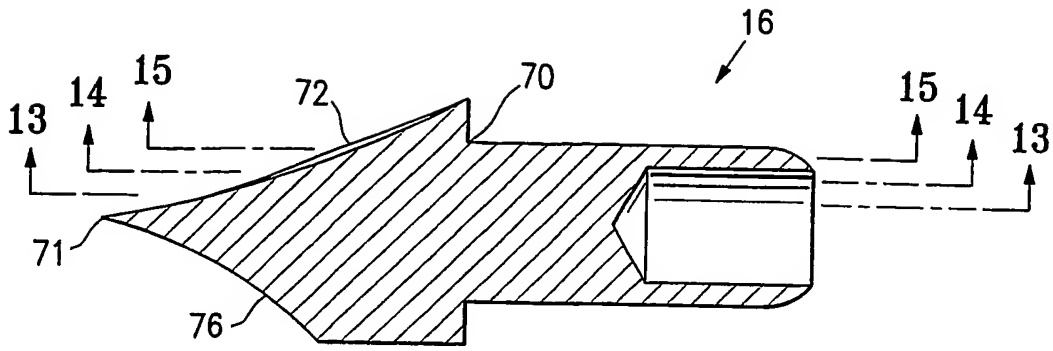


FIG. 12

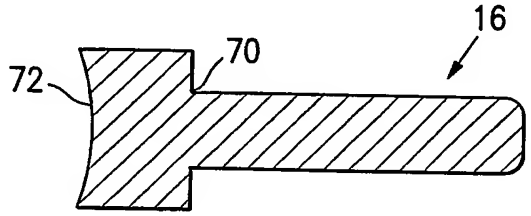


FIG. 13

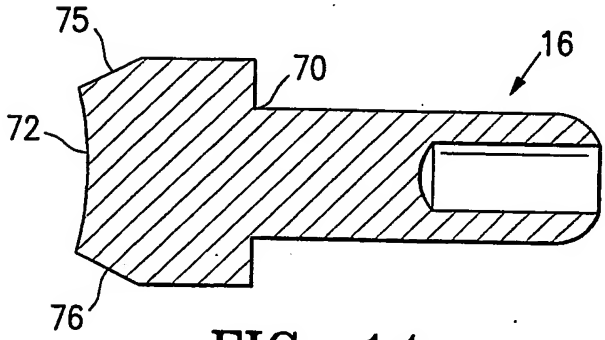


FIG. 14

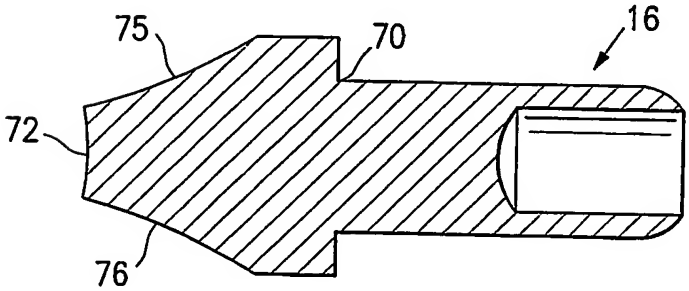


FIG. 15

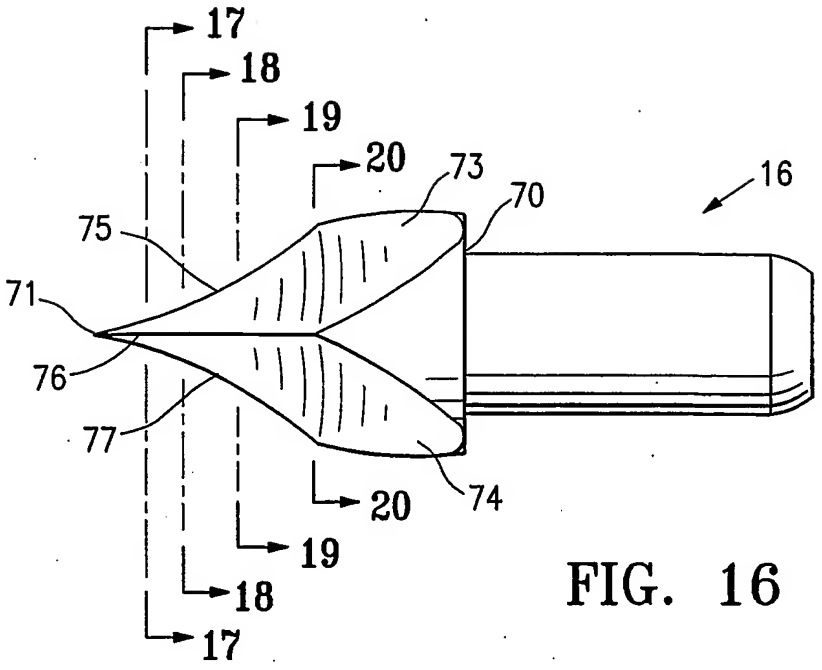


FIG. 16

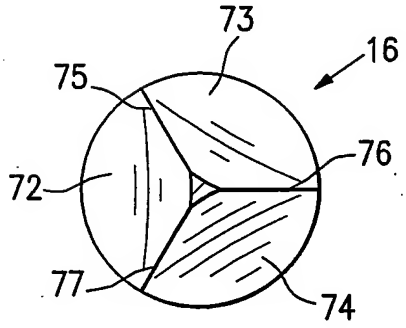


FIG. 17

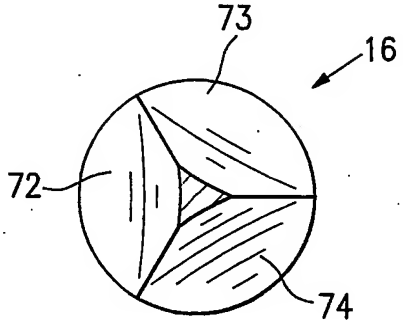


FIG. 18

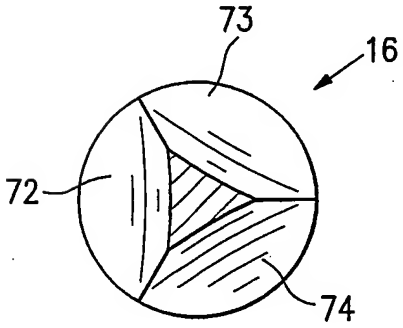


FIG. 19

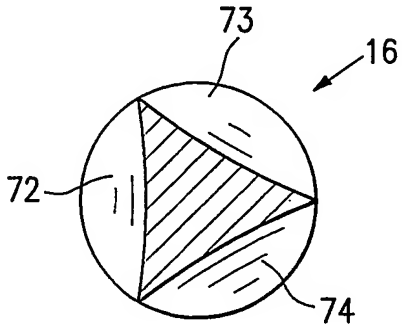


FIG. 20

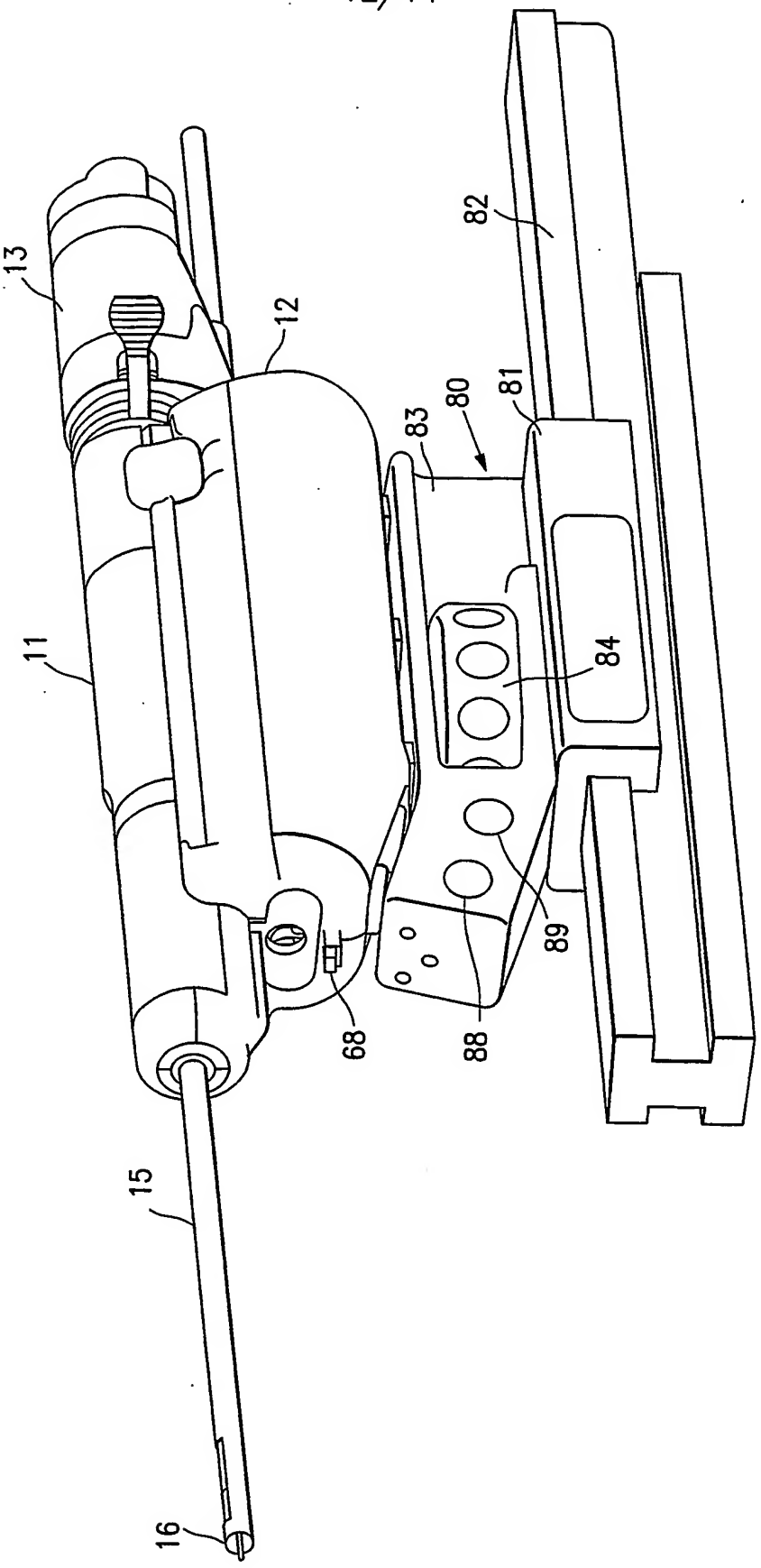


FIG. 21

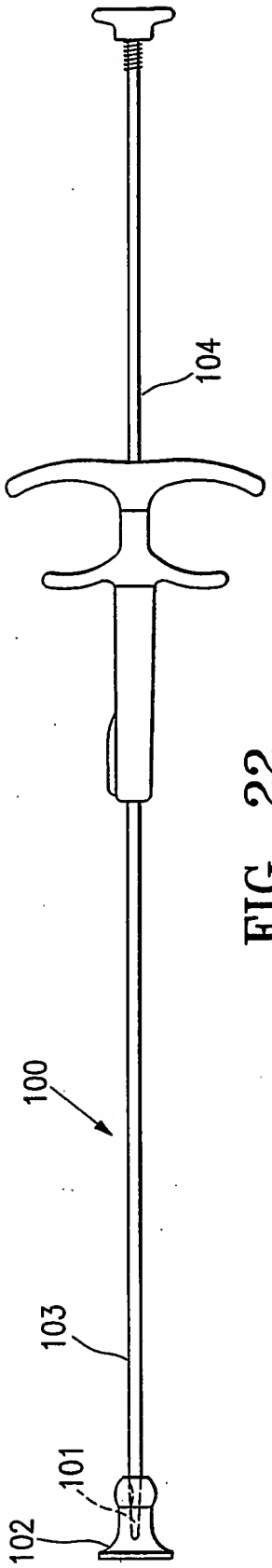


FIG. 22

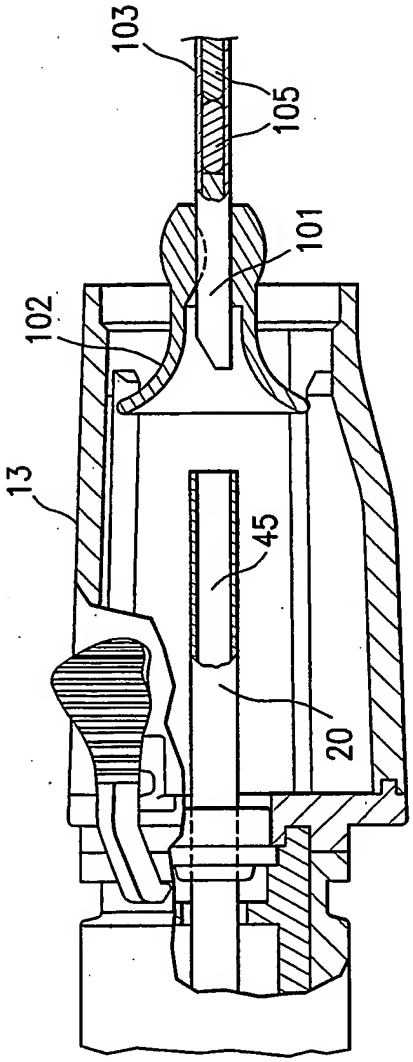


FIG. 23

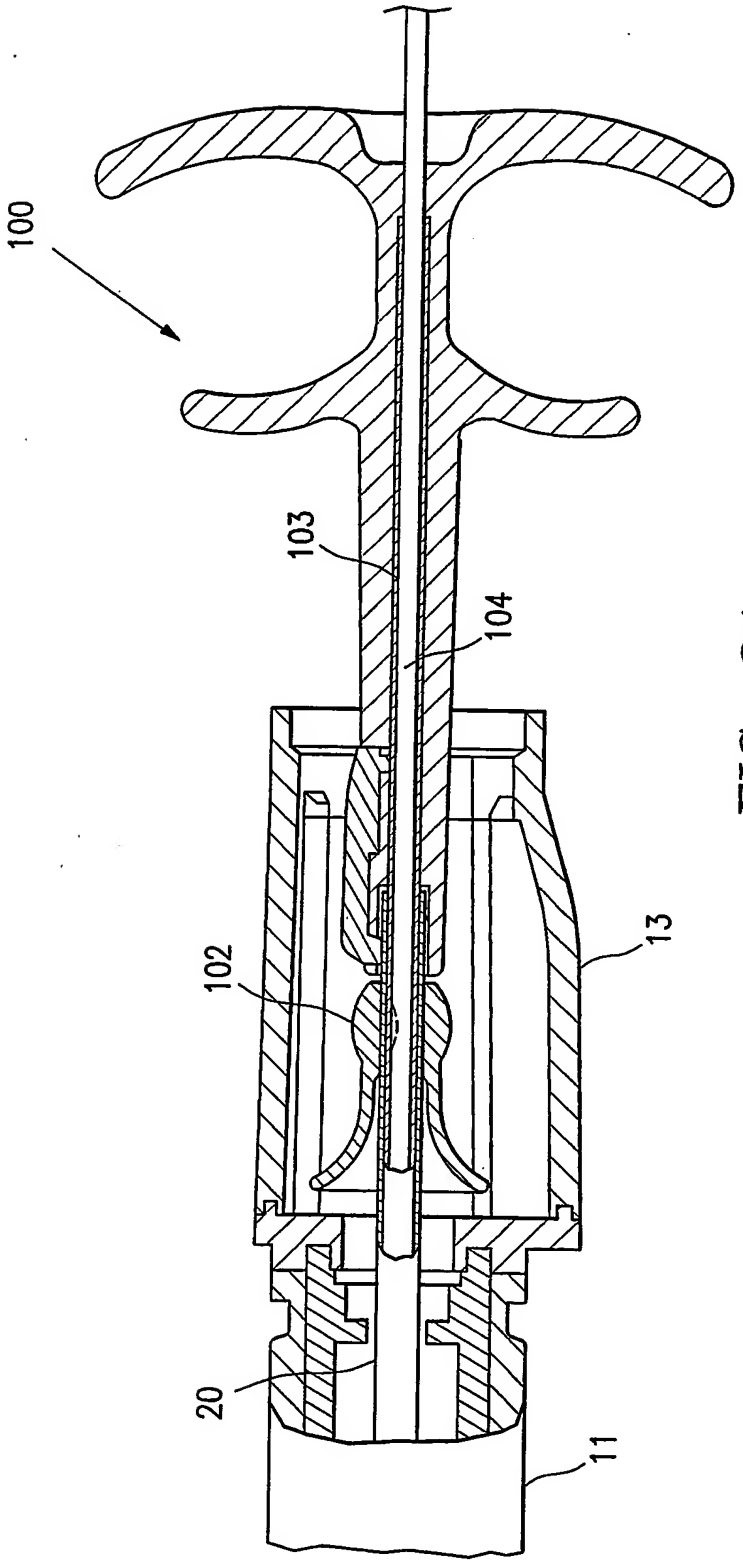


FIG. 24

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 July 2005 (14.07.2005)

PCT

(10) International Publication Number
WO 2005/063126 A3

(51) International Patent Classification[7]: A61B 10/00

(21) International Application Number:
PCT/US2004/043021

(22) International Filing Date:
20 December 2004 (20.12.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/532,277	23 December 2003 (23.12.2003)	US
11/014,413	16 December 2004 (16.12.2004)	US

(71) Applicant *(for all designated States except US)*: **SENORX, INC.** [US/US]; 11 Columbia, Suite A, Aliso Viejo, CA 92656 (US).

(72) Inventors: **SHABAZ, Martin, V.**; 25421 Old Trabuco, Lake Forest, CA 92630 (US). **QUICK, Richard, L.**; 22970 Bouquet Canyon, Mission Viejo, CA 92692 (US). **LOUW, Frank, R.**; 6188 Paseo Tienda, Carlsbad, CA 92009 (US). **LUBOCK, Paul**; 30 Bethany, Laguna Niguel, CA 92677 (US). **SAFABASH, Jason, H.**; 30 Torres Pointe, Aliso Viejo, CA 92656 (US).

(74) Agent: **LYNCH, Edward, J.**; Duane Morris LLP, One Market, Spear Tower, Suite 2000, San Francisco, CA 94105 (US).

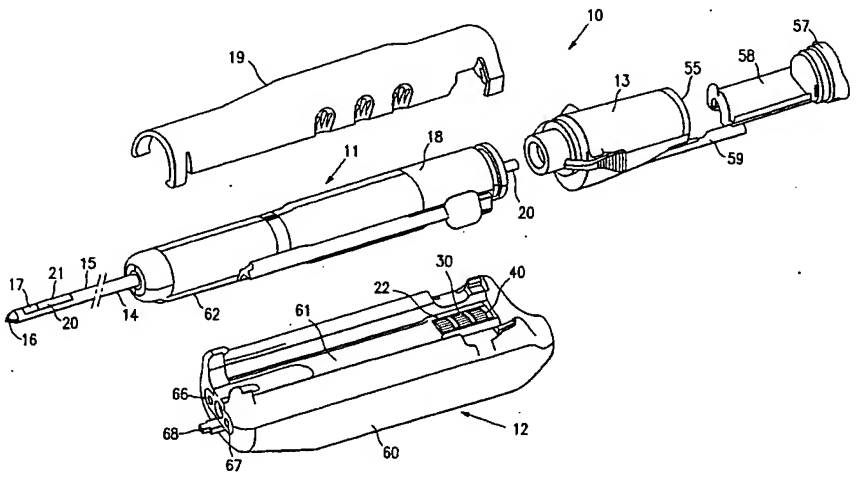
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) Title: BIOPSY DEVICE WITH APERTURE ORIENTATION AND IMPROVED TIP FIELD OF THE INVENTION



(57) Abstract: The invention is directed to a system and device for separating and collecting a tissue specimen from a target site within a patient. The device includes a probe component which is releasably secured to the driver component (12). The probe component has an elongated tubular section (15), a penetrating distal tip (16) and a tissue receiving aperture (17) in the distal end of the tubular section proximal to the distal tip, and a tissue cutting member (20) which is slidably disposed within the probe member to cut a tissue specimen drawn into the interior of the device through the aperture by applying a vacuum (59) to the inner lumen of the tissue cutting member. The driver has drive members (22, 30, 40) for operating the elements of the probe component. The tissue penetrating distal tip preferably has a triple concave curvature shape with three curved cutting edges leading to a sharp distal point.

WO 2005/063126 A3

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
15 September 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/043021

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 980 469 A (BURBANK ET AL) 9 November 1999 (1999-11-09) column 13, line 1 - column 21, line 10; figures 1K-18	1-9,12, 20-25, 43,48-54 10,11, 13,14, 47,56,63
Y	WO 02/22023 A (TYCO HEALTHCARE GROUP LP) 21 March 2002 (2002-03-21) page 20, line 2 - line 9	10,11
Y	US 5 595 185 A (ERLICH ET AL) 21 January 1997 (1997-01-21) column 5, line 11 - line 20	13,14
A	US 3 945 375 A (BANKO ET AL) 23 March 1976 (1976-03-23) column 5, line 42 - line 64	15-19, 32-39

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 July 2005	26. 07. 2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Herberhold, C

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/043021

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 540 695 B1 (BURBANK FRED ET AL) 1 April 2003 (2003-04-01) column 13, line 29 - line 33	15-19, 32-39
A	US 2003/004407 A1 (CARROLL ROBERT G ET AL) 2 January 2003 (2003-01-02) paragraph '0071!	15-19, 32-39
X Y	US 5 477 862 A (HAAGA ET AL) 26 December 1995 (1995-12-26) column 5, line 17 - column 6, line 30; figures 4-6	57,59-62 63
X Y	US 5 769 086 A (RITCHART ET AL) 23 June 1998 (1998-06-23) figures 1,2	43-46 47
Y	EP 0 970 658 A (ETHICON ENDO-SURGERY, INC) 12 January 2000 (2000-01-12) paragraph '0028!	47
Y	EP 0 966 925 A (ETHICON ENDO-SURGERY, INC) 29 December 1999 (1999-12-29) paragraph '0028!; figure 2	55,56
Y	US 5 320 613 A (HOUGE ET AL) 14 June 1994 (1994-06-14) column 6, line 4 - line 30; figure 9	55,56

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/043021

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-25, 32-43, 48-53

A tissue biopsy system for accessing and collecting one or more tissue specimens from a target site wherein the tubular section is rotated in increments of about 15° to about 45°.

1.1. claims: 13,14

A tissue biopsy system for accessing and collecting one or more tissue specimen including a protective tube disposed about the tubular section.

1.2. claims: 15-19, 32-42

A tissue biopsy system for accessing and collecting one or more tissue specimen wherein the driver component has at least one illuminating element in a distal portion thereof

---

2. claims: 26-31, 57-63

A tissue biopsy system for accessing and collecting one or more tissue specimen wherein the penetrating distal tip has a proximal base a first concave surface a second concave surface which intersects the first concave surface forming therewith a curved cutting edge that leads to the sharp distal point and a third concave surface which intersects the first concave surface forming therewith a second curved curving edge leading to the sharp distal point and which intersects the second concave surface forming therewith a third curved cutting edge that leads to the sharp distal point.

---

3. claims: 44-47

A tissue biopsy system for accessing and collecting one or more tissue specimen with a specific driving mechanism for the cutting element

---

4. claims: 54, 55, 56

A tissue biopsy system for accessing and collecting one or more tissue specimen with a marker delivery device or being adapted to be used with a marker delivery device or a marker delivery device.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/043021

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5980469 A	09-11-1999	US 5775333 A	07-07-1998
		US 5526822 A	18-06-1996
		US 5928164 A	27-07-1999
		CA 2186283 A1	28-09-1995
		EP 0751744 A1	08-01-1997
		JP 3650117 B2	18-05-2005
		JP 9510638 T	28-10-1997
		WO 9525465 A2	28-09-1995
		US 2002120212 A1	29-08-2002
		US 2004019299 A1	29-01-2004
		US 5649547 A	22-07-1997
		US 2001007925 A1	12-07-2001
		US 2002016555 A1	07-02-2002
WO 0222023 A	21-03-2002	US 6712773 B1	30-03-2004
		AU 8528101 A	26-03-2002
		CA 2421964 A1	21-03-2002
		EP 1317211 A1	11-06-2003
		JP 2004508127 T	18-03-2004
		WO 0222023 A1	21-03-2002
		US 2003216667 A1	20-11-2003
US 5595185 A	21-01-1997	WO 9604851 A1	22-02-1996
US 3945375 A	23-03-1976	US 3844272 A	29-10-1974
US 6540695 B1	01-04-2003	US 6471700 B1	29-10-2002
		US 6312429 B1	06-11-2001
		US 2001017137 A1	30-08-2001
		US 6261241 B1	17-07-2001
		US 2002007130 A1	17-01-2002
		US 6331166 B1	18-12-2001
		CA 2445912 A1	11-07-2002
		EP 1351609 A2	15-10-2003
		WO 02053036 A2	11-07-2002
		US 2003144605 A1	31-07-2003
		AU 2771601 A	16-07-2001
		CA 2395225 A1	12-07-2001
		EP 1255499 A2	13-11-2002
		JP 2003518974 T	17-06-2003
		WO 0149184 A2	12-07-2001
		US 2002115943 A1	22-08-2002
		US 2002120211 A1	29-08-2002
		US 2003023239 A1	30-01-2003
		US 6497706 B1	24-12-2002
		US 2001002250 A1	31-05-2001
		US 2004117652 A1	17-06-2004
		US 2002058884 A1	16-05-2002
		US 2002068879 A1	06-06-2002
		US 2005038462 A1	17-02-2005
		AT 280542 T	15-11-2004
		AU 6351800 A	05-02-2001
		CA 2378071 A1	25-01-2001
		DE 60015334 D1	02-12-2004
		EP 1196107 A1	17-04-2002
		JP 2003504148 T	04-02-2003
		WO 0105320 A1	25-01-2001
		US 2002077628 A1	20-06-2002

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/043021

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6540695 B1		AU 2634200 A	18-08-2000
		CA 2360582 A1	03-08-2000
		EP 1146828 A1	24-10-2001
		JP 2002535069 T	22-10-2002
		WO 0044295 A1	03-08-2000
		US 2004204709 A1	14-10-2004
		US 2001039420 A1	08-11-2001
		AU 5926699 A	10-04-2000
		CA 2344641 A1	30-03-2000
		EP 1115345 A2	18-07-2001
		JP 2002526191 T	20-08-2002
		WO 0016697 A2	30-03-2000
		US 6517498 B1	11-02-2003
		US 2005090762 A1	28-04-2005
		US 2001014779 A1	16-08-2001
		AU 5579299 A	21-03-2000
		CA 2341528 A1	09-03-2000
		EP 1109496 A2	27-06-2001
US 2003004407 A1	02-01-2003	US 6484050 B1	19-11-2002
		US 5961458 A	05-10-1999
		AT 274194 T	15-09-2004
		DE 69919576 D1	23-09-2004
		EP 1135699 A2	26-09-2001
		WO 0033105 A2	08-06-2000
		EP 1035801 A1	20-09-2000
		WO 9925248 A1	27-05-1999
US 5477862 A	26-12-1995	CA 2184904 A1	21-09-1995
		EP 0757540 A1	12-02-1997
		JP 9504979 T	20-05-1997
		JP 3076922 B2	14-08-2000
		WO 9524858 A1	21-09-1995
US 5769086 A	23-06-1998	CA 2239614 A1	12-06-1997
		DE 69633640 D1	18-11-2004
		EP 1428477 A1	16-06-2004
		EP 0939604 A1	08-09-1999
		JP 2001515372 T	18-09-2001
		WO 9720504 A1	12-06-1997
EP 0970658 A	12-01-2000	US 6007497 A	28-12-1999
		AU 745526 B2	21-03-2002
		AU 3686399 A	13-01-2000
		CA 2276385 A1	30-12-1999
		EP 1550404 A1	06-07-2005
		EP 0970658 A1	12-01-2000
		JP 2000070273 A	07-03-2000
EP 0966925 A	29-12-1999	US 6261302 B1	17-07-2001
		AU 760565 B2	15-05-2003
		AU 3677199 A	13-01-2000
		CA 2276788 A1	26-12-1999
		DE 69906420 D1	08-05-2003
		DE 69906420 T2	12-02-2004
		EP 0966925 A1	29-12-1999
		ES 2195518 T3	01-12-2003
		JP 2000033089 A	02-02-2000

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/043021

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5320613 A	14-06-1994	NONE	